3 SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary/Statement Certification
Re: K_____

CHECK ONLY ONE:

☑ 1. **510(k) Summary.** Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ 2. **510(k) Statement.** I certify that, in my capacity as of _____ (company), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____
[Signature]

_____
[Typed or Printed Name]

_____
[Date]

SPENCER TECHNOLOGIES TRANSCRANIAL DOPPLER ULTRASOUND SYSTEM TCD 100M

Section 1 Identifying Information

Manufacturer: Spencer Technologies, Inc.

Address: 701 16th Avenue

Seattle, WA 98122 USA

Telephone: (206) 329-7220

Contact: Tony Williams

Manager Quality Assurance/Regulatory Affairs

Name of Device: Spencer Technologies Transcranial Doppler Ultrasound System with 2 MHz Transducer

Section 2 Class and Predicate Information

Classification Name: Ultrasonic Pulsed Doppler System 892.1550, 90 IYN

Diagnostic Ultrasound Transducer, 892.1570, 90 ITX

Common Name: Transcranial Doppler ultrasound system

2 MHz Ultrasound Transducer

Proprietary Name: TCD 100M

PWD13 Transducer

Class: Regulatory Class II

Predicate Device(s): Dantec Medical, Inc., Multi-Dop X, K931801

Dantec Medical, Inc., Multi-Dop S, K926363

MedaSonics, Inc., Cerebrovascular Diagnostic System, K914862

Nicolet Biomedical Inc., Neuroguard, TCD Ultrasound System, K962796

Section 3 Performance Standards

Performance Standards: None.

Conforms to the following voluntary standards: CSA 22.2, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, UL 2601-1.

Section 4 Special Controls

510 (k) Special Report

Section 5 Indications for Use

The TCD 100M transcranial Doppler ultrasound system is intended for use as a diagnostic ultrasound fluid flow analysis system:

- For the measurement of cerebral artery blood velocities to determine the presence of hemodynamically significant deviations from normal values
- To assess arterial cerebral blood flow for the occurrence of microembolic signals

Vessels intended for observation include, but are not limited to, the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral and basilar arteries via the foramen magnum, and the opthalmic artery and intracranial internal cartoid artery via the eye.

The TCD 100M is intended for use during:

- Diagnostic exams
- Surgical interventions

The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

Section 6 Device Description

The TCD 100M is a transcranial Doppler (TCD) diagnostic ultrasound system, with 1 pulse wave Doppler (PWD) transducer that can be used free-hand (or headframe mounted for longer term monitoring). A supplementary m-mode display may be used to help locate blood flow signals, to position the sample gate for Doppler signal, and for detection of emboli signals.

Section 7 General Safety and Effectiveness

The TCD 100M is similar to currently distributed pulsed Doppler ultrasound systems with 2 MHZ transducers intended for transcranial Doppler applications. Maximum acoustic output levels are below pre-amendment levels for acoustic intensity for this application, and for Mechanical Index for all applications. On-screen cautions indicate appropriate power levels for other applications other than transcranial prior to the user beginning an exam. Power levels are displayed at all times during scanning. A standard spectrum display is shown in both viewing formats. The m-mode image is a new presentation of the Doppler signal information and results from processing the standard ultrasonic echoes, from which the spectrogram signal is derived, into a different presentation format. It does not represent a new excitation mode.

Section 8 Acoustic Output

Acoustic Output Reporting Table for Track 1 from *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, September 30, 1997* (*FDA Ultrasound Guidance (1997)*), Table 5-4, page 5-7.

TCD 100M
Acoustic Output Reporting Table for Track 1
Non-Autoscanning Mode

Transducer Model: PWD13 **Operating Mode:** PWD

Application(s): Adult Cephalic

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value				0.70	583	33.7
Associated Acoustic Parameter	$p_{r.3}$		(Mpa)	0.99		
	W_o		(mW)		105	106
	f_c		(MHz)	2.00	2.00	2.00
	z_{sp}		(cm)	3.20	3.20	3.20
	Beam dimensions	x_{-6}	(cm)		0.352	0.350
		y_{-6}	(cm)		0.356	0.354
	PD		(μsec)	3.5		3.5
	PRF		(Hz)	5000		5000
	EBD	Az.	(cm)		1.30	
		Ele.	(cm)		1.30	
Operating Control Conditions	DEPTH		(none)	Deep (82-146mm)	Shallow (22-86mm)	Deep (82-146mm)
	SAMPLE		(none)	Short (3mm)	Long (9mm)	Short (3mm)
	POWER		(%)	100	100	100

Table 1: Acoustic Output Reporting Table – Track 1

Supplemental Cranial Thermal Index (TIC) data derived from *FDA Ultrasound Guidance*, Table 6-3, page 6-9. Estimate per *Output Display Standard* (NEMA UD-3)

Index				TIC
Global Maximum index value				2.17
Assoc Acoustic Parameter	W_o		(mW)	113
	f_c		(MHz)	2.00
	Dim of A_{aprt}	Dia.	(cm)	1.30
Other Information	Focal Length*	FL_x	(cm)	3.3
		FL_y	(cm)	3.3
Operating Control Conditions	Depth		(none)	Shallow (22-86mm)
	Sample		(none)	Long (9mm)
	Power		(%)	100

Table 2: Supplemental Cranial Thermal Index (TIC)

* Measured at I_{SPTA} max.

Section 9 Software

The Operating System is Microsoft Windows 98® English OPK Kit Second Edition X03-79454.

Section 10 Conclusions

The TCD 100M is a computer based ultrasound system intended for transcranial Doppler (TCD), with a single type of pulse wave Doppler transducer that can be used free-hand (or mounted in a headframe for longer term monitoring). This comprises a Track 1 device with output exceeding cephalic limits and maximum Thermal Index Cranial included in the labeling (user manual). An m-mode imageis used to help position the sample gate for Doppler signal, and for detection of embolic signals. The m-mode image does not represent a new insonation mode but rather is an additional display of information from the conventional pulsed Doppler signal. Its use for signal detection is as an aid to the operator and is not diagnostic. Its use to aid embolus detection is an adjunct to detection methods already performed in predicate devices. Accordingly, the Spencer Technologies TCD 100M is believed to be substantially equivalent to devices of the same type that are currently lawfully distributed in interstate commerce in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2000

Spencer Technologies, Inc.
c/o Michael Kwan, Ph.D.
Office Coordinator
Underwriters Laboratories, Inc.®
333 Pfingsten Road
Northbrook, Illinois 60062-2096

Re: K002533
Spencer Technology, Inc.'s Transcranial Doppler (TCD) Ultrasound System, TCD 100M
Regulatory Class: II
Product Code: 90 IYN/21 CFR 892.1550
Dated: August 15, 2000
Received: August 16, 2000

Dear Dr. Kwan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the 2 MHZ Transducer PWD13 intended for use with Spencer Technology, Inc.'s Transcranial Doppler (TCD) Ultrasound System, TCD 100M, as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David G. Segerman

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form, Ultrasound System

Diagnostic Ultrasound Indications for Use Form

ULTRASOUND SYSTEM TCD 100M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic			N	N						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The m-mode is a new presentation of the Doppler signal information and results from processing the standard ultrasonic echoes, from which the spectrogram signal is derived. It does not represent a new excitation mode.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Clayman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002533

Diagnostic Ultrasound Indications for Use Form

2 MHZ TRANSDUCER PWD13

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				N						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David H. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002533